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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
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HM12/0917

RECEIVED
SEP 21 1999

EXAMINER

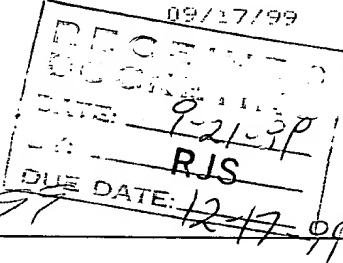
ART UNIT PAPER NUMBER

1813

20

DATE MAILED:

09/17/99



This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- ☒ Responsive to communication(s) filed on June 24, 1999
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire THREE month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2, 5-15, 17-27, 31-38 is/are pending in the application.
- Of the above, claim(s) 7-13, 21-26, 31-38 is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 1, 5, 15, 17-27 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☒ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s) _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

Art Unit: 1615

The Restriction Requirement is made Final.

The method of using the active agent polymer of (I) which comprises (II) is distinct as defined at MPEP 806.05(R) since the (I) polymers may be useful other than as biological disorders treatment agents. For instance, the polymers (I) may be useful as coating agents for prosthetic devices.

Claims 7-13, 21-26, 31-38 are withdrawn from further consideration as not being drawn to the elected invention.

Claims 1, 5-15, 19-27 are rejected under 35 U.S.C. 112, paragraph 1.

A derivatized nucleic acid is not of record in the specification. Undue experimentation is expected to be necessary to derivatize a nucleic acid since the statement at bottom of page 26 “oligopeptides and proteins of increasing chain length can be similarly derivatized with NO” is conjecture since high molecular weight nucleic acids are not expected to be analogous to organic compounds with respect to reactivity in the schemes of working examples IV, V, VI. A theory or claim that nucleic acid can be derivatized by attachment of nitric oxide is not equivalent to definite instructions which can be used prepare such materials. Those in the synthetic polymer area would not be able to proceed with an attempt to use nucleic acids since laboratory setup guidance is not provided. A “use” of an NO derivatized nucleic acid is also absent from the disclosure. Characterization of an NO derivatized nucleic acid would require the same type of spectroscopic data which was given for peptides at the end of each working example.

Art Unit: 1615

It is necessary to provide a Declaration in which the product nitric oxide derivatized nucleic acids are experimentally demonstrated.

The burden is upon the Applicants to explain the reaction conditions such as quantity of reactant(s), type of solvent and temperature to be used to derivatize nucleic acid by the model synthetic sequences which the working examples contain in regard to peptides.

There are many possible sites of attachment in a nucleic acid molecule and thus the predictability of nitric acid group attachment at particular nitrogen is expected to be low.

That considerable experimentation is necessary to prepare nitric oxide protein derivatives is evidenced by the J. E. Saavedra et al Publications submitted to J. Org. Chem. and Bioconjugate Chemistry. Claims limited to polymeric backbones close in structure to those Publications would be considered to be supported.

The Opinion of Dr. Joseph A. Hrabie has been carefully considered, but same amounts to a research proposal rather than accomplished fact. The discussion of purine base derivatization is noted, but the specification contains no disclosure regarding such a method. The present application does not disclose in an enabling manner the derivatizations of the J. Org. Chem. and Bioconjugate submissions.

Finally, the claims are not limited to derivatization according to the reaction scheme sequence drawn out in the working example pages, the only disclosed methods which could be successfully used by those skilled in the art. The reaction schemes of the specification do not utilize biopolymers such as nucleic acid.

Art Unit: 1615

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 5-15 and 19-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stamler Proc. Nat. Acad. Sci. Vol. 92, January 1992.

It would be obvious to prepare derivatives of biopolymers which contain nitric oxide groups in view of the synthesis information of Stamler et al. That is, the disclosure of the instant specification discusses possible use to derivatize biopolymers such as nucleic acids, whereas Stamler et al derivatize proteins in real experiments. It would be obvious to apply the derivatization technique of Stamler et al. to attach nitric oxide - containing groups to nucleic acids.

References (A)-(D), (U), are cited to complete the record.

P. Kulkosky; CV

9/15/99

A handwritten signature in black ink, appearing to read 'P. Kulkosky', with a stylized, cursive script.

PETER F. KULKOSKY
PRIMARY EXAMINER